OBJECTIVES: Switzerland's regulation of prices for reimbursed drugs is based on referencing across countries and within the therapeutic class for products with comparators. The SwissHTA initiative involving all key stakeholders in the health care systems (sickness funds, industry, physicians, academia, Kantons) has published consensus papers for new benefit criteria and measurements. **METHODS:** A comparison was executed comparing the new proposed criteria against benefit assessments in HTA systems in Germany and the UK. **RESULTS:** In terms of clinical benefit assessment the suggestion by SwissHTA follows accepted evidence-based methods. In comparison to Germany the Swiss approach suggests a pragmatic application by applying disease specific standards. This disease focus allows also accepting different levels of evidence given the characteristics of the disease. This pragmatic approach allows Swiss decision-makers accepting lower evidence levels at the time of launch (e.g. in case of comparison with non-Swiss standard-of-care) coupled with a post-reimbursement commitment. The Swiss method looks similar to the medical benefit application by NICE. In terms of health economic (HE) evaluations SwissHTA suggests focusing on technical efficiency instead of QALY comparisons across the whole system as in the UK. Such an approach avoids the application of arbitrarily defined cost-effectiveness thresholds. In Germany the HE focus is solely based on cost comparisons. In terms of decision-making in Germany the focus is based on an assessment of the available evidence against a theoretical maximum standard of evidence. In the UK coverage decisions are based on cost-effectiveness assessments allowing for context-specific adjustments. In the SwissHTA recommendation a multi-criteria decision-making should be applied with an equal focus on all key aspects (e.g. clinical benefit, public relevance, social preferences, etc.). **CONCLUSIONS:** In comparison to HTA systems in Germany and UK the SwissHTA recommendations seems to be more pragmatic and would follow a broader multi-criteria decision making approach.

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PRODUCT QUALITY ASPECT IN REIMBURSEMENT OF MEDICAL DEVICES: COMPARISON OF TURKEY VERSUS EUROPE

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OBJECTIVES: FDA has long recognized that dramatic increase in adverse event reports due to medical devices and recalls may reflect quality flaws. While some of this increase can be explicated by FDA's greater outreach emphasizing reporting requirements, failures in product design and manufacturing process cause more than half of all product recalls. Therefore, FDA's concern regarding low quality products remains. In the EU, medical device pre-market quality is assured by CE mark authorization. This regulation is the prerequisite for market registration also for Turkey. However, due to heterogeneity and complexity of devices, manufacturers, imported devices and multiple use environments, there is strong need for post-market quality assurance. **METHODS:** This study investigates whether post-market quality assurance (measured by less adverse events/better health outcomes) can be applied through local reimbursement policies. First, it is investigated whether there are reimbursement rules in Europe acting as post-market quality assurance. Then, a comparison is made with Turkey's existing reimbursement scheme. **RESULTS:** Our comparative analysis reveals only Belgium and France implement quality or brand based reimbursement rules. In Turkey, there is no quality based reimbursement scheme; however current reimbursement application guideline requirements may act as a gate keeper for lower quality products. Our Results show in addition to pre-market regulations, post-market quality can be assured by local reimbursement authorities. **CONCLUSIONS:** There are several opportunities to improve quality assurance and reduce risk across medical device industry; i.e. enhancing visibility of comparative quality to harness market forces and increasing the collaboration between stakeholders. From health policy perspective, implementation of new value based reimbursement models require providers to prove that they're meeting quality standards and benefitting patients while cutting costs. Therefore, while value based payment contracts are still in their infancy in Europe and Turkey, they will have a direct impact on the assurance of continued medical device quality.

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A COMPARISON OF FACTORS INFLUENCING REIMBURSEMENT AND COVERAGE DECISIONS IN SCOTLAND (SMC), THE NETHERLANDS (NZI) AND GERMANY (G-BA)

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OBJECTIVES: In Germany, Scotland and the Netherlands, the manufacturer's submission is assessed by the HTA bodies; G-BA, SMC and NZi. In Germany, the submitted evidence is used to assess the drug's additional benefit, followed by price-rebate negotiations with the GKV-Spitzenverband. In Scotland and the Netherlands, the submitted evidence is evaluated for reimbursement decision. This study aims to compare factors that influence the reimbursement recommendation by SMC and NZi, the additional benefit by G-BA and the rebate by GKV-Spitzenverband. **METHODS:** Three databases were created consisting of 463 SMC applications, 262 NZi evaluations and 68 G-BA decisions. Logistic regression analyses were conducted to assess the impact of the submitted evidence on the recommendation by SMC and NZi and the effect of variables on the additional therapeutic benefit by G-BA. The impact of variables on the rebate was examined through linear regression analysis. **RESULTS:** In Scotland, 57% of the applications received positive recommendation and the NZi recommended 83% of the submissions. In Germany, 60.3% of the products demonstrated an additional benefit. In Scotland, the multivariate analyses showed that the performance of a cost-minimization analysis and beneficial cost-effectiveness outcomes were the strongest positive predictors of the recommendation. In the Netherlands, univariate analyses showed that the decision was significantly affected by whether the product under assessment was a life-saving intervention and the inclusion of (positive) economic evidence. In Germany, univariate analyses demonstrated that the therapeutic indication and the overall survival benefit, along with improved morbidity and adverse events meaningfully influenced the benefit assessment. Analysis showed that the rebate was significantly reduced by 13% for products that demonstrated additional benefit. **CONCLUSIONS:** Even though reimbursement submission requirements of Scotland and the Netherlands look similar, SMC weights the cost-effectiveness outcomes more, while NZi focuses on the variables related to additional clinical benefit; variables that also significantly influence G-BA's decision.

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A COMPARISON OF ADDITIONAL BENEFIT SCORES IN GERMANY (GBA) AND FRANCE (HAS)

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OBJECTIVES: The Pharmaceutical Market Restructuring Act (AMNOG) has brought a sustainable change to the reimbursement of new drugs in Germany. The G-BA assesses the additional benefit of the drug, compared to an appropriate therapy. AMNOG law is perceived to be one of the toughest drug evaluation process in Europe. In France the high authority for health (HAS) assesses the level of improvement of actual benefit (IAB). The objective of this study was to compare the additional benefit score issued under AMNOG law to IAB scores granted by the HAS. **METHODS:** All G-BA's additional benefit scores until June 1st 2014 and HAS IAB score were compared. **RESULTS:** In Germany, a total of 76 completed early benefit assessments. From the best available score perspective, the G-BA assessed the additional benefit as considerable in 20% of drugs assessed (score 2), as minor in 30% of drugs assessed (score 3), as unquantifiable in 8% of drugs assessed (Score 4) and as none in 38% of drugs assessed (Score 5). No drug has been granted a major additional benefit (score 1) and 4% of drugs were directly allocated to a reference price group. In France, the transparency committee granted a major improvement in 0.2% of cases (IAB I), an important improvement in 1.3% of cases (IAB II), a moderate improvement 2.5% of cases (IAB III), a minor improvement in 9,2% of cases (IAB 4) and no clinical improvement in 86.8% of cases (IAB V). **CONCLUSIONS:** This study shows that the G-BA assigned an additional benefit (scores from 1 to 4) to more than half of drugs whereas the HAS granted an additional benefice rating to less than 14% of case. This study suggests that there is a more favourable benefit rating in Germany than in France.

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HTA STATUS OF BIOSIMLARS ACROSS THE UK AND IRELAND

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OBJECTIVES: Biosimilars have the potential to revolutionise the health care landscape by realising cost savings over originator biologics and thus increasing access to innovative medicines. The biosimilars marketplace in the UK and Ireland is relatively new, however the landscape is rapidly developing. The objective of this analysis was to map the HTA status of biosimilars in the UK and Ireland to provide insight for stakeholders involved in the assessment of new biosimilars. **METHODS:** The HTA status of all EMA authorised biosimilars was identified by searching the websites of all four HTA agencies in the UK and Ireland, namely, NICE, the SMC, the AWMSG, and the NCPE. All previously assessed medicines and on-going technology appraisals were screened for the inclusion of biosimilars using the non-proprietary (common name) and proprietary (brand) names. **RESULTS:** Sixteen (84%) of the nineteen biosimilars submitted to the EMA have been authorised, eleven of which (69%) have been considered by HTA agencies. The SMC has approved 100% of the biosimilars it has considered (n=7); the largest positive reimbursement rate amongst all HTA agencies considered. The AWMSG has considered the largest number of biosimilars (n=11), of which five, (45%) received a positive reimbursement status. Both NICE and the NCPE have approved one biosimilar, however three additional biosimilars are currently being considered by NICE. **CONCLUSIONS:** The reimbursement status of biosimilars in the UK and Ireland is not consistent across HTA agencies. The timing of HTA submissions to different HTA agencies may play an important factor in the reimbursement status of biosimilars given that this landscape is relatively new and assessment processes vary. Marketing authorisation holders for biosimilars may want to consider the strategic importance of submitting evidence to each of the HTA agencies in the UK and Ireland, and the impact timing may have on the uptake of their biosimilar.

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DOES NOT REACHING AN AGREEMENT ON THE FINAL NICE SCOPE HAVE ANY IMPACT ON THE FINAL APRAISAL OUTCOME?

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OBJECTIVES: Identifying the right patient population, comparator and endpoints is key to increase the likelihood of reimbursement. Manufacturers do not always agree with payers' views on these items. Disagreement may lead to funding rejection. We assessed the rate of mismatches between manufacturers and NICE and their impact on the final appraisal outcome. **METHODS:** All manufacturer submissions (MS) from January 2011 until June 2014 were reviewed. For these submissions, the initial proposed scope, the manufacturer's comments, and the final scope and appraisal outcome were analysed. All changes to the initial scope suggested by the manufacturer were recorded and their impact on final outcome investigated. **RESULTS:** In the time period reviewed there were 101 MS of which 7 were suspended and not included in our analysis, while comments were not available for another 18. Manufacturer comments are published for 76 MS. The manufacturer disagreed on ≥1 section of initial scope in 93% (71/76) of MS. The areas where manufacturers and NICE disagreed most commonly are the comparator(s) (43/71; 61%) and population (40/71; 56%) to be assessed. The final scope implemented all and some of the manufacturer's comments in 56% (40/71) and 28% (29/71) of submissions, respectively.